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OPTIMIZATION AND PERSONALIZATION OF RADIOPHARMACEUTICALS IN NUCLEAR MEDICINE

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BACKGROUND-AIM

We describe planning, structural and organizational changes introduced to fulfill the requirements necessary according to NBP-MN for radiopharmaceuticals (RF), in compliance with the ALARA principle and the radioprotection (RP) standards with the aim to improve diagnostic quality and efficacy and to avoid unnecessary patient exposure to radiation, in compliance with safety standards.

METHODS

The necessary legislative alignment resulted in:
- planning and restructuring of our radiopharmacy. The areas have been compartmentalized (preparation/control/extemporaneous preparation) and classified according to NBP-MN/GMP standards and RP directions
- acquisition of devices for the manufacturing of RF (shielded hot cells and isolator A-GMP) and for quality controls (QC) (activimeters, radiochromatograph, etc.)
- redefinition of QC program for devices
- implementation and customization of a software integrated with our RIS, which leads traceability of the whole processes of RF preparation: from the starting material acquisition to the single customized administration
- revision of the procedures for the management of radioactive material from acceptance to waste disposal
- equipment of laboratory to perform QC, including chemical waste management
- definition of RF specifications, implementation of QC procedures to perform before the administration
- all the involved personnel in production, QC tests and release received specific training on RF specific aspects
- implementation of algorithms for customizing the administered activity, taking into account the type of examination and RF, age, medical condition, sex and body surface area of patients. The efficacy of our algorithms in terms of diagnostic efficacy in vivo was evaluated by phantoms studies
- all critical instrumentations were included in a validation master plan and installation qualification, operational qualification and performance qualification were performed for each of them
- training and evaluation of personnel on aseptic technique were performed through media fill tests on pharmaceutical compounding-sterile preparations. Media fill protocols were performed on: preparation of a Tc-99m RF through kit, drawing unit RF dosages from the kit and for PET-RP, preparation of labelling patient autologous tissue.

RESULTS

RF are manufactured in a controlled (environmental and radioactive) areas. All steps take place in self-contained and dedicated facilities to radioactive products. It was implemented a quality assurance system which includes: validation of the equipment, processes, techniques and of the staff involved in the preparations. The process is controlled by use of Standard Operating Procedures, monitoring, training, competency assessment, supervision and change control. Every patient receive a personalized dose of RF.

CONCLUSION

Our adjustment, according both to regulatory procedures for manufacturing RF and to radioprotection rules, has provided a structural and functional reorganization involving environment, job procedures and personnel according to a quality assurance system. The optimization and the global quality improvement we reached has lead to a personalized approach to nuclear medicine investigations.